

**REMARKS**

The Examiner is thanked for the due consideration given the application. The specification has been amended to improve the headings and to provide the date for deposit.

Claims 1-16 are pending in the application. The amended claims address the few indefinite or vague or redundant terms noted in the Official Action on page 2. In order to clarify the wording of Claim 1, Applicant has adopted the expression "vanillin product" which is referred to in the application notably in paragraph [0062] of the corresponding publication US 20070298475, where is taught the precipitation step to provide "a crude vanillin product". The vanillin product provided at this step (ii) is indeed crude but is produced starting from a solution in which vanillin is already substantially free of odoriferous by-products. Support for this added expression is found throughout the specification and notably in paragraph [0020] and paragraph [0042] of the corresponding publication.

The meaning of "from a solution which is or is derived from said biotransformation medium" is to be found in the application as filed notably in paragraph [0017] of the corresponding publication, that is to say when the solution is not the biotransformation medium itself it can be derived from said biotransformation medium after removal of cells (microorganisms) for example.

The material provided at step (iii) is a purified material compared to the crude product obtained through (ii) because the treatment practiced in the application enables to carry away impurities and leaves behind a purified solid vanillin material, report notably at paragraph [0015] and [0016] and/or in paragraph [0041] of the corresponding publication, where the vanillin content of 98-100% is taught, that is to say vanillin of a higher purity.

The antecedent basis of claim 7 has been improved. The amendments to claim 11 find support in paragraph [0020] of the corresponding publication. In amended claim 15, the precise genus of the deposited strain is now designated in the claim as *Amycolatopsis sp.*, since the species of this new strain has not yet been defined by taxonomists. Amended claim 16 is now respectfully submitted to the Examiner in a definite and non-confusing terminology.

No new matter is believed to be added to the application by this amendment.

**Rejection Under 35 USC §112, Second Paragraph**

Claims 1-16 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The comments in the Official Action have been considered, and the claims have been accordingly amended to be clear, definite and have full antecedent basis.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

**Rejection Under 35 USC §112, First Paragraph**

Claims 15 and 16 have been rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

The Official Action asserts that the invention appears to employ a specific strain of *Amycolatopsis* deposited as IMI 390106 or mutants thereof, and it is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. The Official Action further asserts that it is unclear if the starting materials were readily available to the public at the time of invention.

In response, Applicant confirms that deposited strain has been accepted for deposit under the Budapest Treaty. Reference to the culture collection with name and address is made on page 7 of the specification (paragraph 0027 of the publication). The date of the deposit is 03/02/2003 and has been entered into the specification.

Following the suggestions on page 4 of the Official Action but subject to the condition set forth at following paragraph (b) of 37 CFR §1.808, The Applicant agrees to declare in accordance with 37 CFR §1.808 about "Furnishing of samples".

(a) A deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Director to be entitled thereto under § 1.14 and 35 U.S.C. 122, and

(2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:

(1) Is in writing or other tangible form and dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and of the deposit date is 03/02/2003 introduced into the specification.

In accordance with the comments at page 4 of the Official action but subject to the condition set forth at following paragraph (b) of 37 CFR §1.808 Thus Applicant agrees to

declare following Art 37 CFR §1.808 about "Furnishing of samples".

(a) A deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Director to be entitled thereto under § 1.14 and 35 U.S.C. 122, and

(2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:

(1) Is in writing or other tangible form and dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and

(3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

(c) Upon request made to the Office, the Office will certify whether a deposit has been stated to have been made under

conditions which make it available to the public as of the issue date of the patent grant provided the request contains:

- (1) The name and address of the depository;
- (2) The accession number given to the deposit;
- (3) The patent number and issue date of the patent referring to the deposit; and
- (4) The name and address of the requesting party.

The above assurances can be re-submitted in the form of a Declaration, if the Examiner desires.

Therefore, the application sets forth subject matter that enables one of skill in the art to practice the present invention without recourse to undue experimentation.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

**Rejection Under 35 USC §103(a)**

Claims 1-13 have been rejected under 35 USC §103(a) as being unpatentable over Rabenhorst et al. (U.S. Patent No. 6,133,003) taken with Muheim et al. (U.S. Patent No. 6,235,507) and Makin (U.S. Patent No. 4,474,994). This rejection is respectfully traversed.

First, it is notable that the cited art represents the conventional art that the present invention supersedes, as was discussed in the specification, notably in paragraphs [0006] and [0007] of the corresponding publication.

As was clearly and unambiguously seen by the present inventors, the prior art did not address the problem of getting, with *Actinomycetales* microorganisms - whether called *Amycolatopsis sp.* or *Streptomyces setonii* - a biotransformation medium devoid of odoriferous by-products, considered as contaminants by the present inventors.

Rabenhorst et al., from H&R (Haarman & Reeimer), did not address this very problem. In order to reduce to practice the Rabenhorst et al. method as taught in U.S. Patent No. 6,133,003, Applicant obtained authorized samples through the EPO and the culture collection, namely DSMZ DSM 9991 and 9992. Applicant could not obtain any such vanillin free of contaminants but rather, in all the experimentations made in parallel, they got no vanillin at all with DSM 9991 and very little vanillin in the biotransformation medium always along with unwanted vanillic acid in the case of DSM 9992. Additionally, Applicant found in parallel experiments that DSM 9992 produces much vanillic acid and noticeable guaiacol when used according to the present invention method first step (i) to (ii) contrary to the new strain created by the inventors which produced vanillin and only vanillin and at a high level.

Moreover Muheim et al., from Givaudan, teach in the working example of their patent how to obtain vanillin + guaiacol both at a reasonably high concentration.

These teachings would have deterred a man skill in the art from using any of these strains to solve his problem and to provide a final vanillin material which meets internationally recognized criteria for a "bio-vanillin", see paragraphs [0045 to 0047] of the publication of the present invention, notably in terms of absence of odorous impurity (off-aroma) such as guaiacol, vinylguaiacol, eugenol, isoeugenol or presence at no more than ca 100 ppm in the solid vanillin material (please report to paragraph [0045]).

In order to arrive at the inventive solution, the present inventors unexpectedly found for the first time that, before any purification step, one must consider getting a biotransformation medium with special features such as the here above mentioned ones, that is to say in particular absence of off-aroma and also preferably low remaining concentrations of unreacted ferulic acid (please see paragraph [0042] of the publication) in said biotransformation medium.

The problem set forth in the present application is solved via the use of determined *Actinomycetales* microorganisms created by the inventors.

So contrary to what is said in the Official Action, Applicant respectfully submits that it was not a simple question of adjustment/optimization of variables taken from the cited prior art and that the creation, by the present inventors, of *Actinomycetales* microorganisms able to provide a vanillin



material as defined in the present application was totally unforeseeable from the prior art and gave unexpected results never taught in the literature (please see paragraphs [0027] to [0036] of the publication).

In addition one of the microorganisms to carry out the best mode of the present invention was deposited at a recognized culture collection, namely CABI, the accession number thereof being given in the present application.

Thus according to Applicant, the present inventive method to produce a new "bio-vanillin" is not *prima facie* obvious. Moreover the industrial success of vanillin produced by the present inventive method shows, if needed, that there was a long felt need for such an aroma product.

One of ordinary skill and creativity would thus not produce a claimed embodiment of the present invention from a knowledge of the applied art references. A *prima facie* case of unpatentability has thus not been made.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

### **Conclusion**

The Examiner is thanked for considering the Information Disclosure Statement filed September 28, 2005 and for making the references therein of record in the application. Prior art of record but not utilized is believed to be non-pertinent to the instant claims.

The Examiner is respectfully requested to contact the Applicant's representative below if there are any remaining issues that need resolving.

As it is believed that no issues remain the issuance of a Notice of Allowability is respectfully solicited.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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